UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,599	02/12/2001	Wouter E. Roorda	M-9246 US	3819

7590 10/09/2002

Cameron Kerrigan
Squire Sanders & Dempsey LLP
One Maritime Plaza
Suite 300
San Francisco, CA 94111-3492

EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/781,599	Applicant(s) ROORDA ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11-13 and 21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11-13 and 21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Election of Species, received by the Office on July 19, 2002.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6, 11-13, and 21-31, in Paper No. 6 is acknowledged. It is requested that applicant cancel the non-elected claims in the Response to this Office Action. Due to applicant's election without traverse, the restriction requirement is made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11-13, and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,879,713 to Roth *et al.*. Roth *et al.* teach targeted delivery via biodegradable polymers, more specifically to provide a means for locally administering bioactive molecules to tissues or cells in a patient in a controlled, sustained manner (abstract, and column 2, lines 49-52). Roth *et al.* teach that the polymeric carrier is in the form of microparticles that are targeted

by size and degradation and release properties to particular regions of the body, especially the alveoli and capillaries (column 3, lines 22-26). Roth *et al.* also teach that microparticles with specific diameters are selected to lodge in particular regions of the body, such as in a capillary (column 7, lines 33-40). Angiogenic factors are listed as possible biologically active agents which can be incorporated in the polymeric carrier , i.e., within microparticles which are immobilized in the carrier (column 9, lines 60-64). Roth *et al.* also teach that the microparticles can be administered once, or may be divided into smaller doses to be administered at varying intervals of time, depending on the release rate of the particle, and the desired dosage (column 13, lines 41-44). Furthermore, Roth *et al.* teach that the microparticles selectively lodge at the targeted site within the vascular system of the animal where release is desired for a sufficient amount of time to permit controlled release of a therapeutically effective amount of the biologically active molecules (column 17, claim 1).

Roth *et al.* do not specifically teach that the particle be embolized for less than one week. However, Roth *et al.* do state that the microparticle should lodge for a sufficient amount of time to permit controlled release of the active agent. It is the position of the examiner that one of ordinary skill in the art would consider the time a manipulatable parameter, depending upon the active agent used and the desired effect.

Additionally, Roth *et al.* do not specifically teach that the particle should be placed above, below or in between the occlusions or blocks in the vessels. However, it is the position of the examiner that this is not a patentable distinction. The purpose of the Roth disclosure is to deliver biologically active agents to a targeted site in the vascular system wherever treatment is needed. Furthermore, Roth *et al.* achieve the same result as that sought by applicant, which is

the vascularization or the target area. Absent evidence to the contrary, it appears that the particulars as to whether the microparticles are introduced below or above the occlusion does not render patentable distinction to the claim. Any evidence provided to rebut this statement must be shown to depend solely on the actual placement of the microparticles with respect to the occlusion.

It is the position of the examiner that the teachings of Roth *et al.* render applicant's instant claims obvious. One of ordinary skill in the art would have been motivated, by the teachings of Roth *et al.*, to introduce microparticles containing angiogenesis factors, into the vascular system, in an effort to deliver the active agent at a targeted site, and therefore increase vascularization. The expected result would be successful targeted delivery of an active agent. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A.E. Pulliam
October 3, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600